U.S. Environmental Protection Agency

Public Hearing on

Strengthening Transparency in Regulatory Science

9:00 a.m. to 5:45 p.m.

Tuesday, July 17, 2018

U.S. Environmental Protection Agency

1201 Constitution Avenue N.W.

Washington, DC 20460

US EPA Panel Members:

MS. JENNIFER ORME-ZAVALETA (Hearing Official)

MR. CHRIS ROBBINS (Hearing Official)

MS. MARY ELLEN RADZIKOWSKI (Hearing Official)

MS. CAROLYN HUBBARD (Hearing Official)

MR. BRUCE RODAN (Hearing Official)

MR. KEVIN TEICHMAN

MS. MARIA DOA

MS. LYNN FLOWERS

MS. SUSAN BURDEN

MR. LOU D'AMICO

Non-EPA Panel Members:

Ms. LAUREN HALL, SC&A INC.

Ms. LESLEY STOBERT, SC&A INC.

P R O C E E D I N G S

MS. ORME-ZAVALETA: So I want to say hello, and I want to thank you all for coming. We are now calling this public hearing into session. My name is Jennifer Orme-Zevaleta, and I'm with EPA's Office of Research and Development, and I'll be one of the hearing officials today.

Kevin Teichman is also with me from the Office of Research and Development, and we also have some contract staff, Nanishka , Lauren, and Lesley from SC&A Incorporated, who will be helping with the logistics.

The purpose of today's hearing is to accept public comments on EPA's proposed rule, "Strengthening the Transparency in Regulatory Science."

EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding, and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was

published in the Federal Register on April 30, 2018 (83 FR 18768), and EPA is proposing this rule under the authority of 5 U.S.C 301, in addition to the authorities that were listed in the proposed rule document dated April 30th of 2018.

So my role today is to ensure that EPA receives your comments in an orderly fashion, and then -- although EPA panel members here may ask clarifying questions, the intent of this hearing is to hear from you and to listen to your comments and not to discuss or debate the proposal.

So now, for a few housekeeping and ground rules. Please refrain from interrupting speakers or asking questions, shouting, noise making, or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately, and listeners on the phone can hear the oral testimonies.

For everyone's awareness, the hearing is

open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio, and photos. We ask that you not cause any disruption to those who are testifying or observing the hearing.

There is no formal lunch break, so you may leave for lunch and return to the hearing, but just be advised that you'll need to clear security again if you do that.

If you would like to make an oral comment on today's hearing and did not preregister to speak, please see the hearing staff just outside here at the door at the registration table, and they'll be able to sign you up.

If you would like to provide written comments to the official record, you may hand-submit it to EPA staff today, or mail it, fax it, or e-mail it, your comment. So see the staff at the registration table for instructions on how to submit written comments.

There is a comment box at the

registration table where you can leave hard copies of your oral testimony, or written copies. All comments received will be included in the official docket.

If you submit written comments, it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision.

EPA has extended the comment period and written comments must now be received on or before August 16th of 2018. So EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making any other comments that are not related to this action.

EPA will not provide responses during the hearing, rather EPA will prepare a written summary of comments received that include responses. The Response to Comments document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments

submitted during the public comment period have been considered.

The hearing is being recorded by a court reporter who will be preparing a verbatim record of this hearing, so please speak clearly and slowly into the microphone so that the court reporter can record your comments accurately. A copy of the transcript will be placed in the docket. And this hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier. And it's divided into three sessions. 8:00 a.m. to 12:00 p.m., 12:00 to 4:00, and 4:00 to 8:00.

Public restrooms are located on both sides down the hall, men's to the left, women's to the right, and we will have staff escort you so that you're able to get through the security point and be able to come back. And please note the

location of emergency exits, primarily as you come in and you know, out where you entered this morning will be the main emergency exit for you.

So please take a moment to silence your cell phones. Speakers should have been given a sticker on entry that lists your assigned session, and if you plan to speak and have not received a sticker, please go back to the registration table so they can give you one.

For this session, the 8:00 a.m. to 12:00 p.m. session, the speaker sticker color is neon green so we can see you. Speakers will be called to the speaker's table, which is located right across from us, and will be coming up in pairs to that speaker's table. When it's your turn to speak, please come up to the table. Watch your step as you come up the steps over there, and state and spell your name slowly so that we can have that for the record. And if you are appearing on behalf of someone else or some organization, be sure to clear that -- make that clear as well. If you are not in the room when

it's your turn to speak, I will call you after all other speakers have made their oral arguments.

Each speaker is allotted five minutes for remarks, elected and appointed government officials may be provided additional time since they are representing large groups of constituents. Speakers will be notified when their time is ended. We have a time keeping system just over here. It runs by the yellow -- green, yellow, and red-light system. So when you begin to speak the green light will come on and you have five minutes. When you have one-minute left to speak you'll see a yellow light. And then when the red light appears, your time is up. At that moment I will ask you to wrap up your comments so that we can make room for the next speaker to come forward.

Speakers Numbers 1 and 2, if you could go ahead and please come on up and take your seat at the speaker's table. We will start with Speaker Number 1. And again, if I could ask you to please speak directly into the microphone and state and

spell your name for the record.

And if I could ask, Speakers 3 and 4, if you could just stand at the steps so that you'll be ready, and we'll be able to keep this moving. So, Speaker Number 1.

MR. STEICHEN: Good morning. My name is Ted Steichen, and it's S-T-E-I-C-H-E-N, and I am representing the American Petroleum Industry.

API is the only national trade association -- boy, it's not very bright here. Sorry. The American Petroleum Institute is the only national trade association with all facets of the oil and natural gas industry which supports 10.3 million U.S. speakers (sic).

Sorry. I'm having a little trouble this morning.

All right. So, supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. Our 620 corporate members from large integrative oil companies to small independent companies comprise all segments of the industry. API members are producers, refiners, suppliers,

retailers, pipe line operators, and marine transporters as well as service supply companies supporting most of the national energy.

The members of API are dedicated to continuous improvement in compatibility with their operations with the environment, while environmentally, economically developing energy resources, supplying high-quality products and services to consumers.

Our members recognize the responsibility to work with the public, the government, and others to develop and use natural resources in an environmentally sound manner that protects the health and safety of employees and the public.

API supports the use of sound science for a critical component of public policy, to the extent possible and consistent with the protections of other compelling interests, such as privacy, trade secrets, intellectual property, and other confidentiality protections, data and analysis used in establishing or evaluating environmental health, welfare and economic impacts

should be transparent and reproducible and available as early as possible in the rulemaking process.

Transparency and reproducibility should be able to underly -- also be underlying data and information such as environmental and economic impact data and models that are utilized in protecting and predicting the costs, benefits, market impacts, and environmental effects of specific regulations.

API members are aware that there are obstacles to full transparency and reproducibility, and are committed to working with other stakeholders in developing practices and maximize science transparency while preserving existing confidential strictures.

The EPA -- as the EPA goes forward with this rulemaking, API recommends the following principles be followed. Openness to science and related findings underpinning the laws, regulations, standards, and guidance documents. Reproducibility of research and associated

findings, including fully annotated data, methodologies, model inputs, code and other critical information that support the conclusions of research. All of these should be available to the public.

The inclusion of clear requirements to ensure that the data underline the decision-making are publicly available in a manner sufficient for independent validation as much as practicable. Privacy concerns are important, but advances in encryption technology and blinding of data may make it possible to enhance transparency while ensure privacy as necessary to comply with the law.

Protection for confidential business information used in the regulatory process and supporting actions should also be taken into account, explicitly addressing and highlighting uncertainties in data, models, and analysis when utilizing those studies in decision-making. Broad application of these principles to inform the use of policy for setting scientific, economic, and

environment impact requirements and models that are designed to protect health and environment, engaging stakeholders as early as possible in the decision-making process to ensure application of data transparency principles for studies to be included, and to address how those studies have not been reproduced or are not reproducible will be considered in the process, application of these principles as early as possible in the pre-rule making stage, as technical support documents are prepared.

In closing, as described above, API supports the use of sound transparent science and public policy making, and we plan to submit written comments to the docket.

MS. ORME-ZAVALETA: Thank you.

MS. FELD: Good morning. My name is Jodi Feld, J-O-D-I F-E-L-D, and I'm the Chief Scientist in the New York City office of the New York State Attorney General's Environmental Protection Bureau.

On behalf of New York Attorney General,

Barbara Underwood, I thank you for the opportunity to speak before you today. The Office strongly opposes EPA's proposed rule to limit the use of science in agency rulemakings. The proposed rule was developed without any input from the scientific community and has been widely criticized by the scientific and public health communities. It is vague, poorly reasoned, and violates fundamental legal requirements for a valid rulemaking.

Most importantly, while the proposed rule has the stated purpose of strengthening the foundation of EPA's regulatory actions, it would have the opposite effect. It would exclude relevant probative scientific studies, models, and other information from EPA decision-making that have been validated by peer review, simply because the underlying data are not available to the public. The proposed rule broadly and squarely conflicts with core EPA statutory duties. It violates the very federal laws that EPA is required to uphold by limiting EPA's access to the

most current, best available, and generally accepted science that these laws mandate be used by EPA in developing new rules and standards. Quite simply, it is bad science.

It departs abruptly from the best practices of the scientific community and disregards both well-established reasons why public sharing of all study data is not possible or necessary, and why studies relying on such data demand consideration in agency decision-making.

The result of the proposed rule would be to profoundly weaken EPA's science-based regulatory decision-making, and ultimately its protection of public health in the environment in New York and elsewhere across the nation. We urge EPA to abandon this damaging and misguided effort. It appears that the proposed rule was developed with a total absence of independent scientific input. The proposal offers no rationale for the premise that only studies for which the underlying data are publicly available can be used for decision-making, nor any evidence that EPA's

current approach to selecting studies for decision-making is resulting in scientifically unsound decision-making, or is somehow overly protective of public health and the environment. Hence, at its core, the proposed rule is a solution in search of a problem.

Requiring that study data be publicly available as a prerequisite to its consideration by EPA would be an abrupt and unprecedented break from well-established best practices of the scientific community. The scientific community recognizes what the proposed rule ignores, that there are often very good reasons why some research data simply cannot be fully available to the public, such as the protection of personal privacy and confidentiality.

Within the scientific community the validity of research is judged on multiple grounds, including how well studies are designed, how clearly data are collected, how carefully analysis are performed and described, and how thoroughly findings of related studies are cited.

In other words, within the scientific community studies are validated through rigorous expert peer review. They are not summarily judged and valid and discarded simply because all underlying data cannot be fully shared.

Perhaps the strongest indicator that the proposed rule is flawed as a matter of science is the overwhelmingly negative reception it has received from the scientific community. We are not aware of a single major independent scientific organization that has expressed support for the proposed rule, while many have urged EPA to stop and reconsider the proposal.

Contrary to EPA's position, the proposed rule would certainly hurt states. EPA standards and regulations are a fundamental important to states and actions that affect these standards and regulations directly affect us. In fact, many states, environmental laws, and regulations explicitly adopt EPA standards. By undermining the basis of EPA standards and regulations, the proposed rule would likely have direct damaging

impacts on New York and other states' abilities to protect the health and environment of their residents. These impacts will be felt most historically by our most vulnerable populations, the young, the elderly, and the sick, and those living in communities that have borne a disproportionate share of environmental hazards, including communities of color and low-income communities.

From a legal perspective, the proposed rule fails to meet the most fundamental requirements for a valid rulemaking. It is exceedingly vague, creating many more questions than it answers. For example, exactly how, when, and to what the rule will be applied is entirely unclear. And critical information such as its actual cost is entirely missing.

In May, the New York Attorney General, joined by seven other attorneys general, wrote to then, Administrator Pruitt, expressing strong opposition to the proposed rule and calling for it to be withdrawn. Today, the State of New York

renews our call to Acting Administrator Wheeler to withdraw the proposed rule.

I thank you for your time and for providing me with an opportunity to speak on this important matter.

MS. LAUREN HALL: Thank you. If we could have Speakers 3 and 4 come to the table, and then 5 and 6 on-deck?

MR. SUSSMAN: Good morning. My name is Bob Sussman, and I am a former EPA official in the Clinton and Obama --

MS. HALL: Could you bring your microphone --

MR. SUSSMAN: -- administrations --

MS. HALL: Yes, thank you.

MR. SUSSMAN: -- and now a consultant and an attorney.

I'm here today representing Safer Chemicals, Healthy Families, which leads a coalition of 450 organizations and businesses united by a common concern about toxic chemicals in our homes, places of work, and products we use

every day.

I believe that the EPA proposal we are discussing today is flawed and misconceived. In the name of transparency, it will burden EPA scientists with unnecessary and costly procedures that run counter to the Agency's long-standing obligation to base public health decisions on the best available science.

The premise of the proposal is that unless EPA can guarantee full public access to a study's underlying data, the study must be deemed unreliable and should play no role in assessing a pollutant or chemical's effects on public health. This premise ignores the many ways in which the scientific community, regulators, and the public have traditionally determined the quality and relevance of scientific evidence.

Study reports typically explain the protocols use to gather data, the methods used for data analysis, the doses or exposure concentrations at which effects were and were not observed, the nature, severity, and incidence of

such effects, and any unusual occurrences that may affect interpretation of the results.

This information plays an important role in the peer review process, informing the judgment of independent reviewers as to whether a study is worthy of publication in the scientific literature. Agency reviewers likewise consider these indicators of reliability in deciding how much weight a study deserves in making judgments about hazard and risk.

In principle, no one disputes the benefits of improving access to underlying data. The goals of open science have received support from several organizations in leading scientific journals and research institutions. These voluntary efforts, however, do not justify the unprecedented step of requiring EPA to guarantee access to the underlying data for every study it may use for decision-making, and to forfeit the ability to consider a study if this requirement has not been met.

EPA scientists working on risk and hazard

assessments collect and review thousands of studies. Published reports of these studies typically do not include all underlying data. In such cases, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data.

Even with diligent efforts by EPA, there are many reasons why disclosure of data sufficient to replicate a study may be impossible. The EPA proposal duly notes these obstacles to study replication and provides that exemptions may be granted on a case-by-case basis. But an exemption process will add to the considerable cost and effort required to implement the proposed rule and will undoubtedly result in disputes and even litigation over whether exemptions are justified. Is the damage it will inflict on the quality and timeliness of EPA scientists justified by the benefits of the proposed rule?

EPA leaders have painted a bleak picture of EPA reliance on quote, "secret science"

developed behind, quote, "closed doors," based on data that has, quote, "been withheld from the American people."

This is not the reality that I experienced in my several years at EPA. I saw a very different reality. I saw EPA science assessments providing an exhaustive and critical review of relevant studies, and a full explanation of how they're being interpreted. I saw extensive information about each study being placed in the public record. I saw public comment and peer review of all EPA assessments. And of course, as part of public comment, members of the regulatory community had an opportunity at any time to replicate studies they deemed flawed.

In short, the problem that the proposed rule seeks to fix is imaginary. In conclusion, the Agency's leadership needs to fundamentally rethink the proposed rule. The stakes for EPA science and the protection of public health are simply too high to finalize a proposal which is deeply problematic and unnecessary. Thank you.

MS. ORME-ZAVALETA: Thank you.

DR. ROSENBERG: Good morning. I am Dr. Andrew Rosenberg, R-O-S-E-N-B-E-R-G. I'm the Director of the Center for Science and Democracy at the Union of Concerned Scientists. And we advocate for the role of science and public policy.

I'm here today to ask that you rescind this proposed rule because it would only restrict EPA's ability to use the best available science to fulfill its mission of protecting public health and the environment, while doing nothing to improve transparency and decision-making.

First and foremost, the proposal is fatally flawed because it provides almost no justification of analysis of the impacts of the proposed change in policy. There is no cost-benefit analysis of the rule with respect to the agency, and external researches, nor how it would affect EPA's mission and critical work.

Additionally, the proposal would affect -- effectively prevent the EPA from using many

kinds of scientific studies vital to its decision-making. This includes, but it is not limited to studies that rely on personal health data, confidential business information, intellectual property, or older studies where authors and data sources may not be accessible.

Without the ability to use this scientific information EPA would be unable to meet its mission and statutory obligations. This proposal would make it significantly harder for EPA to use the best available science to protect the public, including from harmful emissions of hazardous air pollutants, particulate matter and ozone, exposure to dangerous chemicals and commerce, drinking water contaminated with toxic chemicals, such as PFAS or lead.

Further, CBO has calculated that such restrictions would substantially increase costs and burdens to an agency that is already experiencing budget cuts, reorganizations and understaffing, thus undermining the ability of EPA to make decisions based on science.

The proposed rule could also prevent the Agency from addressing the impacts of dangerous chemicals at low concentrations where direct measurements are very difficult. This would have the effect of leaving Americans unprotected, even when there was clear indication of harm to human health.

I have over 30 years of experience in government service, academia, and non-profit leadership. I've offered -- authored or reviewed hundreds of peer-reviewed scientific papers. As part of my government service I worked as a scientist and in a policy position at a regulatory agency, and universities as a faculty member and dean. I understand how agencies use science in policy making, how research at universities is conducted, and how these entities incorporate best practices of transparency into their scientific work. As a frequent peer reviewer, I do not review the raw data for studies, since that would tell me little. I review the research questions, the methods that summarize data, the results and

conclusions in order to assess the quality of the work. EPA's proposed rule would do nothing to improve transparency for scientists, policy makers, or the public.

Crafting the rule without consulting with the scientific community is a fatal error for this proposal. Even the Agency's own Science Advisory Board has noted the need to consult with scientists in any further development of this proposal.

A further fatal flaw is that the proposed rule would replace scientific evidence with political judgment. The rule would grant the EPA administrator broad authority to exclude individual studies or entire decisions from being subject to its provisions. Decisions on which science is to rely on should be made by the Agency's scientific experts based on established criteria for best available science.

Five minutes is not enough time to cover all the problems with this proposal. At best, this proposed rule is a misguided attempt at

transparency. At worst, it is a back-door attempt to prevent EPA from protecting public health. UCS supports real transparency reforms. We support scientific integrity policies that prevent political interference in scientific analysis and reporting. We do not believe researchers should be put in the absurd position of choosing between protecting study participant privacy or informing the EPA's effort to protect public health and safety.

On behalf of the Union of Concerned Scientists, and I have 500,000 supporters, I urge the EPA not to move forward with this rulemaking and to continue to allow agency scientists and policy analysts to use the best science available to inform their work. Thank you very much.

MS. HALL: Thank you. Would Paul Tonko and Suzanne Bonamici please approach the speaker's table. Speakers A and B, respectively. And Speakers 5, Daniel Greenbaum, and 6, Jennifer McPartland, please take your seats at the on-deck circle.

MR. TONKO: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. TONKO: Can I begin? Okay. Thank you. Good morning and thank you for the opportunity to address the panel.

I am Congressman Paul Tonko. I represent the 20th Congressional District of New York State, more specifically the Capital Region and Mohawk Valley, an area rich in environmental stewardship.

As the Energy and Commerce, Environment Subcommittee ranking member, I have come here today to express grave concerns about the Environment Protection Agency's proposed rule published on April 30th of 2018, entitled "Strengthening Transparency in Regulatory Science."

This proposal would severely limit the types of research that EPA could take into account when developing policies. It has been cloaked in arguments about transparency. But let's all admit here that this emperor has no clothes. This has nothing to do with transparency. It is a thinly

veiled campaign to limit serious and highly credible scientific research that supports critical regulatory action.

This administration has used this bad faith argument about transparency to say that the many studies, including many epidemiological studies that rely on private, personal, medical data should be excluded entirely from EPA rulemaking. Why would a science-driver public agency undertake such a radical departure from existing and widely accepted scientific standards? I have yet to hear a credible answer to this question that is not rooted in favors to industry polluters.

The current political leadership at EPA has shown a pattern of bad faith in pushing policies that undermine this Agency's -- EPA's mission, and the public trust.

Today's proposal and its false claims about transparency are consistent with that pattern; a fact that was put on full display when the administration realized its broad approach

would hurt regulated industries too, since many EPA chemical reviews rely upon confidential business information. To get around this, the rule would give the EPA administrator complete discretion to exempt studies, especially or essentially guaranteeing that political interests will always matter more than science. That's why I refer to this policy as selective science.

This proposed rule would be used to erode landmark achievements in public health and environmental safety. For example, we know the Clean Power Plan would have led to reductions in pollution that were predicted to prevent some 3,600 premature deaths, 19,000 asthma attacks in children, and 300,000 missed school and work days each year. Many of these health benefits were partially determined by landmark clean air studies like the Harvard Six Cities Study.

Opponents of Clean Air Act protections would like nothing more than to see such landmark public health findings excluded from EPA reviews. I'm not here speaking alone. Nearly 1,000

scientists in many leading scientific organizations are united in vocally opposing this policy. Countless everyday Americans stand with us too, with many more listening in and watching for news to see if anyone in a position to do something about this will finally admit the obvious; this is not about transparency. This is not about protecting human health or our environment. This emperor, again, has no clothes.

This rule would limit the scientific research available to EPA policy makers as they draft public protections and environmental guidelines. I implore EPA to put science and public interest ahead of political and special interests, and withdraw this rule, ill-conceived, that's based on -- its negative impacts on science and public health. A very discouraging and concerning proposal. And I just felt compelled to come here today and vehemently speak against it.

MS. ORME-ZAVALETA: Thank you, sir.

MS. BONAMICI: Thank you. Good morning.

MS. ORME-ZAVALETA: Good morning.

MS. BONAMICI: And thank you to Acting Administrator Wheeler and Director Sinks. I am Suzanne Bonamici. I represent the First Congressional District of the State of Oregon. I serve on the House Committee on Science, Space, and Technology, where I am the ranking Democrat on the Subcommittee on Environment. I appreciate the opportunity to testify before you today.

I am opposed to the Environmental Protection Agency's proposed rule titled, "Strengthening Transparency in Regulatory Science." The proposed rule would impede, if not eradicate the EPA's ability to protect Americans from significant risks to human health and to the environment by limiting the scope of research that the EPA could consider in making decisions.

The proposed rule perpetuates the incorrect notion that the science the EPA relies on is somehow hidden. It is not. This misconception is based on conflating the meaning of secret and confidential. None of the information used by the EPA is secret. Some of

the information may be confidential if, for example, it includes the personal health information of individuals who participated in a study.

As a cornerstone of its regulatory process, the EPA relies on peer-reviewed science. The EPA already publicly discloses studies that support regulatory action. The proposed rule simply attempts to block access to good science. Much of the science that is used to inform regulatory actions is developed outside of the agency. Scientific studies often include personal information and other confidential data. Because this data is legally protected from disclosure, the EPA would be forced to ignore valuable information discovered during their research, because it contains confidential information. This would have chilling consequences for the EPA and for every person who benefits from clean air and clean water.

It is also deeply troubling that the proposed rule is inconsistent with the Agency's

statutory obligation to use the best available science as required in the Toxic Substances Control Act, Safe Drinking Water Act, and Clean Water Act. The proposed rule would preclude the use of a range of scientific research that has long been used to safeguard the public.

There is also tremendous uncertainty whether the proposed rule would retroactively apply to existing standards and regulations. Retroactive application would severely undermine existing public health and environmental protections that keep the public safe and healthy.

Transparency is a laudable goal, and it could be accomplished through collaboration with, and input from the scientific community. It is noteworthy that thousands of scientists and many leading scientific originations also propose this proposed rule. If the proposed rule is implemented it is possible, or even likely, that scientists, organizations, and research institutions will be less inclined to participate in EPA funded research because of the risk of

improperly disclosing personal information. It may also be more challenging for researchers to recruit participants for their studies because of the fear that personal data could be shared.

Over the last few years, the House Committee on Science, Space, and Technology has considered several iterations of legislation that have many similarities to the proposed rule. I have been a vocal opponent of these bills for the reasons I just stated.

I also want to note that despite repeated efforts by the majority, the so-called secret science legislation has not passed both chambers. Congress has the sole constitutional authority to legislate, and this proposed rule is an administrative attempt to circumvent the legislative process. I strongly urge you to withdraw this proposed rule. It will undermine scientific integrity, jeopardize bedrock public health and environmental standards, and endanger the EPA's ability to protect the American people, which is its mission.

Thank you for the consideration of my testimony.

MS. ORME-ZAVALETA: Thank you both for coming.

MR. TONKO: Our pleasure.

MS. HALL: Would Daniel Greenbaum, Speaker Number 5 and Speaker Number 6, Jennifer McPartland, please approach the speaker's table. And would Speaker Number 7, David Michaels and Speaker Number 8, Paul Billings, please take a seat in the on-deck circle.

MR. GREENBAUM: Let there be light. And there was light.

My name is Daniel Greenbaum. That's green, like the color, B-A-U-M. I'm the President of the Health Effects Institute, and I'm very pleased on behalf of the Health Effects Institute to provide these brief oral comments today. We are preparing and will submit much more detailed written comments.

As many in this audience know, HEI has a longstanding commitment to the principles being --

attempting to be addressed by this proposal, producing science of the highest integrity and quality with special attention to issues of reproducibility and transparency.

This includes rigorous research and statistical design, subject to competition, continuous oversight, data quality assurance audits, and more, extensive efforts that test all findings against a wide range of different statistical techniques and assumptions, intensive and independent peer review with all results published, and an active data access policy which for nearly 20 years has been working to ensure access to underlying data for all HEI funded studies.

In our view, reproducibility is a critical challenge for science. Can the results of an important study be reproduced? However, in our view the most effective way to test reproducibility and the validity of science is not necessarily to simply reproduce the same results in the same data sets. Rather it is most

important to answer the question, "Are the results consistent when tested in other independent studies?" For example, studies that use new and different data sets not affiliated with the original studies. Studies that have different investigators applying the same and/or alternative statistical techniques. And studies that test the sensitivity of the results against a wide range of possible other explanations like smoking or socioeconomic status.

In a limited number of cases where there are not comparable studies, it may be useful to gain access to the original study data and analytic codes to allow for independent evaluation. Can the original results be replicated, and are they robust to a wide range of alternative assumptions, models, and potential confounders? This is, of course, exactly what the Health Effects Institute did when we conduced an independent rigorous reanalysis of the Harvard Six Cities and American Cancer Society studies. And I've attached and will submit the summary

description of that reanalysis from HEI's final report.

This approach can and did provide comprehensive assurance of the quality, integrity, and validity of the original results. However, this is a highly cost-intensive and time-consuming endeavor, which should only be applied in cases where there are only one or just a few studies in a particular arena.

HEI also agrees with the continued need to enhance transparency and data access, but would note that these issues are not new. We've had our own data access policy for over 20 years, and have been -- and they've been addressed now for over 15 yeas by administrations from both parties, and by the scientific community. This is -- it included guidelines for the Information Quality Act adopted by OIRA in 2002, numerous actions by the scientific community and journals to enhance access, and most recently the requirements for enhanced data access across the federal government promulgated by OSTP in February 2013.

We would strongly urge EPA to review the progress already made under these several major initiatives and to carefully consider whether or not there are additional efforts that could further enhance transparency and to do so before proceeding with a final ruling.

Finally, access to private medical information is essential to conducting high quality and reproducible air quality and health research. There are of course longstanding federal rules for protecting the privacy of individual medical information of the subjects of studies. And gaining access to data from older studies may be difficult, but given the privacy commitments that were made to study subjects in the past.

However, there are today, several means to make such data available to investigators with appropriate privacy protections. Medicare makes it available, federal research data centers make it available, and many investigators already have been taking advantage of these.

Although it is possible, as some have suggested, to create a depersonalized data set by stripping all personal identifiers, such as address, date of birth, et cetera, it's not possible to conduct a high-quality air pollution and health study without knowing the location of those being studied. I.e., Where do they live and what are the sources and levels of their air pollution exposure? So it can't be simply put on a disk and handed out.

Thank you for this opportunity to testify. We look forward to submitting our detailed written comments, and would welcome the opportunity to further assist EPA in these efforts to ensure that the widest array of science is available for decisions.

MS. ORME-ZAVALETA: Thank you.

MS. McPARTLAND: Good morning. My name is Jennifer McPartland, M-C-P-A-R-T-L-A-N-D, and I'm a Senior Scientist at Environment Defense Fund.

EPA's proposed rule represents a

disregard for the Agency's core mission, protection of human health and the environment. Under the guise of transparency, EPA's proposal handcuffs the Agency's use of best available science in violation of many of its statutes. If finalized, the rule will erode critical public health protections, and with them, the scientific integrity and public trust of the agency.

EPA's censored science proposal would prohibit EPA's use of critical scientific studies in developing regulatory requirements unless all the data underlying the studies have been made public. As the authors of this proposal know well, this unnecessary and unworkable standard would effectively bar the Agency from using high-quality scientific research in studying public health safeguards.

The data underlying many scientific studies are not publicly available and cannot be made publicly available. For example, research involving human subjects often rely on medical or other personal information; information that

researchers cannot make public.

Additionally, advances in data science have made it increasingly more challenging to effectively deidentify study subjects and protect their privacy. In other instances, studies may have been published decades ago and the underlying data are no longer available. It is exactly these types of studies that EPA and other authorities use to protect people from harmful environmental exposures like lead, formaldehyde, methylene chloride, benzyne, arsenic, and perchlorate, just to name a few. It is the science generated by our most prestigious scientific institutions. It is the knowledge we rely on to ensure our water is safe to drink, our air is safe to breath, and our land is safe for our children to play.

Beyond jeopardizing critical public health protections, the proposed rule completely disregards established effectiveness mechanisms used to vet scientific research including peer-review, data sharing agreements, and consensus in findings across multiple studies. Indeed, EPA

provides no explanation or justification, showing that this proposal would improve upon these established mechanisms.

The proposed rule also raises several troubling concepts that are contrary to scientific best practices and chemical assessment, as discussed extensively in the Seminole National Academy's report, Science and Decisions.

Specifically, the proposed rule ignores the report's conclusions that thresholds of effect for chemical exposures are the exception rather than the rule, given by a logical and exposure variability across the population. The rule also seeks to demote the use of health protective defaults and risk assessment, again at odds with the recommendations of the National Academies.

Additionally, the proposal gives more value to studies in employ of a variety of dose response models, an approach that can be misleading. Multiple bad analysis does not make a study more credible.

More broadly, the proposed rule seeks to

codify scientific practices and irregulation. It is a consistently frowned upon approach given the continuously evolving nature of science. EPA's development of the proposal also represents a total disregard for process. The Agency sidestepped review by its external Scientific Advisory Board, which has now voiced serious concerns about the proposal and has recommended that it undergo full SAB review before possible finalization.

The White House OMB review of the proposal was also quite dubious, involving a revision to the original date its review had been completed to seemingly align with the fact that former Administrator Pruitt had signed the proposed rule a day prior. The final OMB review process took course over just a few days, an impossible amount of time for any legitimate interagency review of the complex scientific issues at stake in this rulemaking, even though they have implications for all other federal agencies that rely on sound science.

Not surprisingly, the proposed rule does not grapple with the challenging steps necessary for legitimate effort to support greater data availability. It does not consider the digital infrastructure that would be required to make underlying study data publicly available in a secure manner, nor the resources needed for researchers in the Agency to use and maintain such a system.

Indeed, the congressional budget office estimated that a similar piece of legislation would cost millions of dollars. Americans need and expect the EPA to use the best available science. Right now, Americans across the country are drinking water contaminated with per- and polyfluoroalkyl substances, or PFASs.

In May, EPA publicly committed to initiating steps to regulate two of the most well-studied, PFOA and PFOS, toxic substances linked to cancer, thyroid effects, and reproductive harm. Some of the best available data on PFOA comes from the C8 Health Project, which involved a community-

wide assessment of 69,000 residents living around Parkersburg, West Virginia, who had been exposed to PFOA for decades. Studies resulting from the project will be critical to EPA as it takes steps to address PFOA and PFOS, yet the censored science proposal would make it difficult, if not impossible for EPA to rely on those studies.

EPA's censored science proposal serves the interest of polluters, not the public. It is designed to undermine EPA's use of critical research, EDF supports, meaning full transparency and science, and the ongoing efforts in the scientific community provide that transparency. But this proposal is not about transparency. It is about rolling back public health protections and environmental protections.

EDF strongly recommends that EPA withdraw the proposed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 7, David Michaels, and Speaker Number 8, Paul Billings, please approach the speaker's table. And Speaker Number 9, Gary Timm, and

Speaker Number 10, Tyler Smith, please take a seat in the on-deck chairs.

MR. MICHAELS: Good morning. My name is David Michaels, M-I-C-H-A-E-L-S. I'm an epidemiologist and Professor of Environmental and Occupational Health at the George Washington University School of Public Health. I'm also submitting a longer set of comments, copies of which I have available.

From 2009 to January 2017, I served as Assistant Secretary of Labor for OSHA, the longest serving in OSHA's history. From 1998 to 2001, I was Assistant Secretary of Energy for Environment, Safety, and Health, charged with protecting the workers, community, residents, and environment in and around the nation's nuclear weapons complex.

As a scientist who has been deeply involved in promulgating regulations that protect the public's safety, health, and environment, I recognize the importance of open science and using the best available science. However, the proposed rule does not accomplish these goals. Instead, it

would make it more difficult for EPA to use scientific findings to protect public health. I have no doubt it would result in more people made sick by pollution or toxic chemicals that would have been prevented in the absence of this new regulation.

This cynical approach proposed by EPA can be best described as weaponized transparency. Decades ago, when studies started to show that smoking killed not only smokers, but also their non-smoking spouses, the tobacco industry recognized the government would use this evidence to reduce smoking. In response, the tobacco industry demanded access to the raw data of these studies.

Big tobacco turned transparency, an important scientific principal, into a weapon. The strategy worked for tobacco for years, helping to delay regulation and increase the death toll from smoking related illness. Since then, polluters and manufacturers of deadly products have followed big tobacco's playbook. First

supporting legislation, and then when that was unsuccessful, this proposed rule.

If promulgated, this regulation would permit the EPA administrator to deny the Agency use of findings of any study unless the raw data and other related materials are provided to the Agency and posted on the Agency's website. There are no constraints on the administrator. She or he is not required to provide any rationale for rejecting a study because the underlying information is not publicly available.

The underlying justification for this quote/unquote, "transparency proposal," is a caricature of how science really works. It is not sound science. It is something that sounds like science, but isn't.

While in theory, most studies could be reproduced, they rarely are because it's a waste of resources. The scientific enterprise involves approaching the same question in different ways to determine if the results support each other. Reanalyzing the same study over and over is little

different from checking on a surprising newspaper article by buying additional copies of the same newspaper to see if it says the same thing.

Under the provisions of the Administrative Procedures Act, the EPA administrator does not have the authority to refuse to consider any comments submitted to the agency. If he or she thinks it's not valid, inaccurate, or inapplicable, she or he must explain why. Under the EPA submissions, including scientific studies, cannot arbitrarily or capriciously be discarded because the underlying data are not provided.

When I was an OSHA administrator, we wanted to protect the integrity of the science used in setting regulations, so we explored asking for conflict of interest disclosures, similar to those requested by every leading scientific and medical journal.

Our legal experts determined that we could request this disclosure, but we could not reject submissions that failed to include them.

This is a comparable situation; rejecting submitted studies because the underlying data are not available is prohibited under the EPA.

Furthermore, many of the EPA's authorizing laws require the Agency to use the best science. For example, the Clean Air Act mandates that air quality criteria accurately reflect the latest scientific knowledge. In the past the EPA has considered all available studies in issuing these criteria without consideration of the availability of the underlying data. Promulgation of this proposed rule would be a violation of these provisions of the Clean Air Act.

When the loss similar to this NPRM was first considered by congress, the EPA told the Congressional Budget Office that it estimated the cost of gathering, redacting, and posting the data on the public website, at $250,000,000 annually. The cost estimate made by the current administration for a substantially similar law dropped to $1 million a year from $250,000,000 a

year, because in the candid shocking words of the CBO, EPA officials explained this approach would significantly reduce the number of studies the Agency relies on when issuing or proposing covered actions.

In summary, by turning scientific transparency into a virtual weapon, the EPA will inflict severe damage to the nation's scientific enterprise. It will undermine the credibility and application of scientific evidence and impose costs and impediments that will discourage scientists from undertaking studies of great importance. Limiting the EPA's use of scientific evidence in the name of increased transparency will impede its ability to protect the health, safety, and environment of the nation. This proposal must be withdrawn.

MS. ORME-ZAVALETA: Thank you.

MR. BILLINGS: Good morning. I am Paul Billings, B-I-L-L-I-N-G-S, National Senior Vice President Public Policy at the American Lung Association. The American Lung Association is the

nation's oldest voluntary health agency. Our volunteer leaders take great pride in that our work is always grounded in the best available science. The American Lung Association opposes this rule and we urge the EPA to withdraw it.

Make no mistake, this proposal is not an effort to strengthen transparency or improve regulatory science. As I will discuss, this proposal is an effort to exclude important studies whose conclusions, especially studies that shows particulate air pollution causes premature death, are inconvenient. Together with the efforts to discount or exclude benefits from pollution reductions, this is a coordinated effort to ignore the science that is inconvenient to EPA's agenda to roll back regulations that reduce air pollution and save lives.

The EPA Science Advisory Board has asked to review the rule under the authority vested in it by the Environmental Research, Development and Demonstration Authorization Act. The SAB sent a letter to the EPA administrator, raising many of

the same scientific issues of confidentiality, feasibility, and the need for a clearer definition of crucial concepts, such as replication and validation. We urge the EPA to fully consult with the SAB before moving forward with this rule.

After the SAB review is complete, EPA should either withdraw the proposal, or provide an additional opportunity for public comment based on that SAB review.

We are disappointed that the EPA has made this proposal. This is not a new fight. It started in the early 1990s, when the tobacco industry tried to undermine the science that supported EPA's landmark risk assessment that showed that second-hand smoke kills. The tobacco industry and its allies lost a decade-long fight about whether or not second-hand smoke causes lung cancer, heart disease, asthma attacks, and other adverse health effects.

We know many of the details the tobacco industry's efforts, because -- as a result of the landmark tobacco litigation, nearly 90 million

pages of tobacco industry documents are housed at the University of California, San Francisco, Truth Tobacco Industry Documents library. Now we know the truth.

Within this archive are documents that show how PR firms, lawyers, and front groups attempted to undermine the credibility of EPA science. The documents show the tobacco industry launched this effort in the name of sound science that not only attacked the second-hand smoke risk assessment, but EPA's efforts to protect the public from ozone air pollution, radon, pesticides, and more. Remember, in 2006, the big tobacco companies were found guilty of civil racketeering for their decades-long conspiracy to defraud the public about the health risks associated with smoking.

The attack on science continued throughout the 90s, when EPA set the first standard for fine particulate matter. The PM2.5 standard. That national ambient air quality standard has saved thousands of lives. This was a

concerted effort by industry and the tobacco industry and their allies, and make no mistake, tobacco industry did not only focus on second-hand smoke. They attacked all of EPA's science. The other polluters came along for the ride and now we're leading that effort.

There was a concerted effort to undermine the Six Cities Study, and the American Cancer Society study. To address the questions being raised, and we just heard from the Health Effects Institute, the HEI, while protecting patient confidentiality, conducted an independent review of the data and these studies. The HEI reaffirmed the results from those studies. These landmark studies were key to informing the rules that cut PM2.5 pollution over the past two decades. Thousands of people are alive, and millions are breathing easier because of those efforts.

These studies depend on patient participation. Protecting patient confidentiality must be paramount and is key to recruiting study participants. This proposal will censor science,

will exclude important well-done peer-reviewed studies that are informing EPA actions, or will threaten that patient confidentiality. This is an unacceptable choice. EPA must use the best science, with within established frameworks, and not limit access to the best science to inform regulatory decisions. We urge the EPA to withdraw this proposal. Thank you very much.

MS. HALL: Thank you, both.

Would Speaker Number 9, Gary Timm, and Speaker Number 10, Tyler Smith, please come up to the speaker's table. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, please take your seat in the on-deck chairs.

MR. TIMM: Good morning. My name is Gary Timm, G-A-R-Y T-I-M-M. I worked at EPA for 38 years and retired in 2011.

I was Chief of the Chemical Testing Branch in the Office of Pollution, Prevention, and Toxics for 10 of those years. The Chemical Testing Branch is responsible for implementing the

testing provisions of Section 4 of the Toxic Substances Control Act.

Today, my remarks will focus on three things. Our studies traditionally used in support of regulation, and vis-à-vis, the proposed transparency policy, it's interaction with TSCA Section 4, and its interaction with our obligations to accept studies conducted in accordance with OECD test guidelines.

Let us be clear, if EPA had adopted this data transparency limitation and past risk assessments, EPA would not have been able to take many of its historic actions to protect children, families, and the environment. No reduction or elimination of the exposure to children to lead and paint, gasoline and drinking water, no air quality standards for particulate matter and other air pollutants, and the list goes on and on.

The proposed policy would affect assessments that will soon be carried out under TSCA Section 6. TSCA gives EPA the authority to regulate the manufacture, processing, distribution

and commerce, use, and disposal of chemicals. The problem formulation documents, which set forth EPA's approach for assessing the first 10 chemicals under the amended TSCA are open for public comment now.

How these chemicals are assessed will be the model for future assessments. The proposed policy would in fact make it impossible for EPA to consider the full array of well-conducted and peer reviewed scientific studies of the health and environmental effects of pollution. It would bias the body of information in favor of industry supplied studies, since they would all have the means to provide the underlying data.

Assessment of all relevant scientific information is essential in making sound judgments about protecting human health and the environment. And it is a legal requirement in all major environmental legislation.

TSCA also contains provisions to require chemical manufactures to test the chemicals that they manufacture and process. To require industry

to test chemicals under Section 4, EPA must make a set of legal findings. It is the data inadequacy finding that we are interested in today, for it is the nexus between TSCA Section 4, and the proposed transparency policy.

To make this finding, EPA conducts a thorough literature search and usually issues a rule to require studies that have not been published to be submitted to the agency. Typically, the bulk of information considered, however, is studies published in the peer reviewed scientific journals. Despite being accepted by the scientific community, these studies do not meet the transparency requirements of the published rule, since it requires that all raw underlying data and the models used to analyze the data supporting their study are available for public review.

Thus, if the Transparency Rule were in effect, under TSCA Section 4's second finding, EPA would have to judge studies from peer reviewed journals as inadequate. Ignoring this large

category of information would cost industry hundreds of millions of dollars to repeat perfectly good scientifically acceptable studies, which the public would ultimately pay for through higher prices. And it would significant delay, or in some cases preclude assessment and regulation of risks to human health and environment.

Another aspect not discussed in the proposed transparency policy is the obligation of the U.S. to accept data generated in accordance with the Mutual Acceptance of Data treaty. The U.S. and other Organizations for Economic Co-operation and Development member countries realize that differences in testing requirements on countries, meant that companies would in some cases have to retest a chemical in order to market it in other areas. This was needlessly costly and resulted in a delay in obtaining information needed for regulatory assessment.

As a result, the OECD member nations agreed to accept, for regulatory purposes, data generated in accordance with the OECD test

guidelines. Submission of underlying data is not a requirement of the Mutual Acceptance of Data treaty. Therefore, the proposed policy which requires underlying data to be made available to be used for risk assessments would run counter to our obligations under the Mutual Acceptance of Data treaty.

In short, the proposed policy is a trojan horse. I can only conclude that this proposal constitutes fraud, as it is deceptive. Waste, rejecting perfectly valid studies and abuse, for it is arbitrary and capricious.

Thank you for giving me the opportunity to provide comments this morning.

MS. ORME-ZAVALETA: Thank you.

MR. SMITH: Good morning. My name is Tyler Smith. I'm a staff scientist at Earthjustice. We are the largest non-profit environmental law organization in the country.

EPA's proposed rule is an attack on the science used to protect children's health. Simply put, it would weaken risk assessments for

chemicals that harm kids. These chemicals include organophosphate pesticides like chlorpyrifos, which EPA scientists long ago concluded present grave risks to children.

Earthjustice therefore urges the Agency to reconsider its approach and withdraw the proposal immediate. Under the Food Quality Protection Act, EPA is required to abide by an additional safety factor of 10 when setting the level of exposure to a pesticide that may harm infants and children. It is well established that children are more susceptible to the toxicity caused by pesticide exposure than adults. The law therefore requires that EPA take this into account and ensure that the most vulnerable among us are protected.

Under the statute, EPA may decide to apply a different safety factor if, and only if it concludes on the basis of reliable data that such margin will be safe for infants and children. The most reliable data, including epidemiological studies conducted in three different perspective

cohorts clearly establish that prenatal exposure to chlorpyrifos and other organophosphates, harms the developing nervous system. This exposure reduces IQ, and it increases the risk of developmental disorders, such as ADHD.

All of this science was peer reviewed prior to publication, and EPA scientists and the independent experts who serve on the FIFRA Scientific Advisory Panel reviewed it extensively and repeatedly over many years. Accordingly, chlorpyrifos risk assessments conducted in 2014, and again in 2016, included the required safety factor, and both assessments found that exposures exceeded the identified levels of concern.

Accordingly, the EPA proposed banning all uses of chlorpyrifos on food in 2015. But last year, political appointees at the Agency disregarded this science and announced that the Agency would not finalize the proposed ban. EPA now may wait years to reconsider. And it appears that the same political appointees who disregarded the science, now want to weaken the chlorpyrifos

risk assessments in advance of their next review.

Indeed, the pesticide industry responded to EPA's conclusions on chlorpyrifos by proposing novel requirements that are strikingly similar to what the Agency now proposes to do for all science. CropLife America, an industry trade association, asked EPA to quote, "Require access to raw data as a prerequisite to relying on any study to support regulatory decisions," unquote. And Dow AgroSciences, which manufactures chlorpyrifos, also complained in comments that the Agency is not quote, "Secured and shared the raw data underlying the epidemiology studies," unquote.

Now EPA did seek a study -- or, I'm sorry, did seek data from a study conducted at Columbia University. However, Columbia determined that it could not provide all of the requested data without violating its obligations to the mothers and children who had participated in the research.

Notably, EPA did not respond to these

concerns by refusing to consider the Columbia study. Rather, scientists from the Agency and Columbia met to discuss the study in greater detail, and the University produced extensive supplemental analysis in response to agency questions.

Furthermore, Columbia offered to make all of the data available to agency scientists for analysis in a secured facility on Columbia's campus. Now these efforts suggest there are numerous alternatives to the rigid requirements the proposed rule would impose on the use of science and agency rulemaking.

As epidemiologic studies of chlorpyrifos support retaining the safety factor to protect infants and children, EPA may believe that such studies fall within the vague definition of dose response data and models contained in the rule. If so, EPA may believe that the continued efforts by Columbia to protect the hundreds of mothers and children who participated in its research preclude the use of these data because they cannot be made

publicly available.

EPA may believe this precludes the use of other epidemiologic studies as well. As a result, this proposal could be used to avoid protecting infants, children, and others from exposure to chlorpyrifos and more than two dozen other organophosphate pesticides. It is simply outrageous that EPA, an agency charged with utilizing science to protect public health, would do the bidding of the pesticide industry it regulates, and try to circumvent its own scientific conclusions by choosing to ignore the best available science.

I urge the Agency to reconsider this proposal and withdraw this deeply flawed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, approach the speaker's table. And Speaker Number 13, Diana Van Vleet and Speaker Number 14, John Auerbach, please take a seat in the on-deck chairs.

The speakers are reminded to please speak into the mic, and also state who you're speaking for. Thank you.

MS. ECONOMOS: Hi. I am Eugenia Economos, E-U-G-E-N-I-A E-C-O-N-O-M-O-S. I am with the Farmworker Association of Florida. We are a grassroots farmworker organization that's over 35 years old. I say that because it's important to understand that our organization was co-founded by a man who was a farmworker himself. Our staff are almost all former farmworkers. Our board of directors are farmworkers. They're from farmworker families. And I'm here on behalf of our communities who are mostly African/American, Hattian, and Hispanic farmworkers who harvest the food that feed all the rest of us, the food that we eat is harvested by farmworkers in the field who are exposed regularly to pesticides. And I'm here on their behalf.

Our organization is very involved in pesticide health and safety, and in doing that we have participated in community based participatory

research projects, including a four-year project with Emory University that we did. It was funded by NIOSH, and in that study, we looked at farmworkers and in the nursery industry that did ornamental plants in Central Florida, and farmworkers in the fernery industry, which are also ornamental plants.

And we looked at the reproductive health effects of occupational exposures, including occupational exposure to pesticides. We are well-trusted in the community because we are based in our communities and because we are of, by, and for the farmworker communities. And we're able to do these studies because we have the trust of our community members.

In that study with Emory University, we did surveys with 260 women of reproductive age. One of the things we looked at was -- we additionally did urine samples on 100 women, including women that were pregnant, looking at levels of organophosphate pesticides and the pesticide, mancozeb, in their urine.

One of the reasons we chose mancozeb, because that is a fungicide that was implicated in birth defects that happened in Omokollee, Florida in 2004 and 2015, and we wanted to look at the levels of the pesticide in the urine of the women that we studied.

The results of that study showed very high levels of organophosphate pesticides and mancozeb in the urine of the women that we studied, much higher than the NHANES national averages.

We used that information in order to both develop a training for the women about how to protect themselves from pesticides. But we also used that information to write up a paper about -- because mancozeb is coming up for re-review, and we think it's very important to understand the levels that we found of the mancozeb in the urine.

I say that because we would not be able to do that study if we did not have the trust of the people. And we had that trust because we ensured their confidentiality. We would not be

able to do this if there was any sense at all that their confidentiality could be compromised. You're talking about people who are minorities. Many of them are immigrants. They're already under attack in their communities for many other reasons, and if we could not assure their confidentiality, we would not have participation.

I have people come to me all the time with different complaints from their work environments. And it's heartbreaking to me when people come to me and talk about being exposed to pesticides, and then they're afraid to make a report because they're afraid of losing their job, or they're afraid of retaliation.

We would -- we cannot, we would not, we would never engage in studies if we could not ensure that our people, our community would be protected from any kind of revelation of their identities or of their information. So that's why we are opposed to this proposed rule. We're also concerned about that epidemiological data is really important to look at synergistic and

cumulative effects of pesticide exposure, and you cannot find that without doing epidemiological studies. So we are also concerned that we're -- I'm sorry. We're also looking at the body burden of pesticides in the farmworkers that we study, and farmworkers are exposed to multiple different kinds of pesticides. And if you're not looking at epidemiological studies to look at that, then you are ignoring an important role of science in the farmworker community.

I am saying that, I am sitting here, and I just want you to know that even though I'm sitting here, behind me are tens of thousands of farmworkers in Florida and around the country, and I'm here on their behalf. And on their behalf, I'm asking you to reject this rule. Thank you.

MS. ORME-ZAVALETA: Thank you.

MS. LeHURAY: Good morning. My name is Anne LeHuray, L-E-H-U-R-A-Y. And that's Anne, with an E. And I am here as the Executive Director of the Pavement Coatings Technology Council, also I'll call it PCTC.

PCTC, their members manufacture products that are used in pavement maintenance programs to extend the useful life of an asphalt parking lot, for example. Airport surfaces, and the like.

Our members are almost exclusively small family-owned businesses, and their customers, who we also represent, are virtually 100 percent small family -- small and maybe even say micro family owned businesses.

So at PCTC, we strongly support the concept of what EPA is proposing in the "Strengthening Transparency in Regulatory Science" rule, however we urge EPA to go beyond what it has proposed with a goal of improving on EPA's current procedures which lack any meaningful remedies when the Agency relies on science that has been shown to be unreproducible.

The Council supports the efforts of the Agency to ensure that scientific studies, data, and models on which it relies in developing regulations, guidance, and policies are sufficiently transparent. Doing so helps ensure

that others can attempt to reproduce the results in which the Agency bases its regulation, guidance, and policies.

However, the council believes the proposed rule does not go far enough. PCTC has witnessed first-hand the distortions and bad public policy that can result from what has been called in other venues, secret science, by which we mean, science that has been shown not to be reproducible.

And EPA has contributed to this problem. They were not the source of the unproducible science, but they've contributed to the problem by using that unreproducible science, because to use the Agency's words, it is fit for purpose. Meaning, we suppose, that it suits the Agency's desire to regulate, even if the science says that the regulation is unwarranted.

So PCTC's experience causes it to be concerned that the Agency proposes to restrict its increased focus on transparency to only dose response data and models, to only final

regulations, and to only pivotal studies as narrowly defined the proposed rule.

We would note that worldwide scientists and science organizations have recognized the crucial rule of transparency to the very crux of the scientific enterprise, which is, science has to be falsifiable. That means that it has to be reproducible.

At a minimum, the Agency should be as concerned as the publishers of peer reviewed science journals, that all the science it considers is possibly key or pivotal to a right to a regulatory purpose, any regulatory purpose meets the standard of transparency.

EPA's role is to translate and distill research results into regulations, guidance, and policies that have significant impacts in the real world. It is therefore the obligation of EPA to ensure that it uses the best available science, which by definition includes science that has been shown to be reproducible on any issue of any important EPA policy making.

Now to promote the idea of use of reproducible science and transparency, and an understanding in all agency actions, PCTC has two specific recommendations. One is that it gives preference to studies, not just when industry submits a study as part of let's say registering a pesticide, this requires that that study has to follow GLP, Good Laboratory Procedures -- Good Laboratory Practices.

GLP is a formal program. It relies on, like OECD, guidance, methods, test methods. But there's also a thing called the Spirit of OECD, which simply means following good standard scientific practice.

So we recommend and go into detail in our written comments about that the GLP should be given preference in all science that all -- that EPA considers in any of its policy making decisions. And we also have a specific recommendation about how the Office of the Science Advisor should consider combining the roles of the information quality function at EPA, and the

Office of Scientific Integrity, and I thank you very much for your attention and we expand on this in our written comments.

MS. HALL: Thank you very much.

Would Speaker Number 13, Diana Van Vleet, and Speaker Number 14, John Auerbach, please come up to the speaker's table. And Speaker Numbers 15, Harvey Fernbach, and 16, Joseph Stanko, please take a seat on the on-deck chairs.

MS. VAN VLEET: Hello. My name is Diana Van Vleet, D-I-A-N-A, Van Vleet, V-A-N V-L-E-E-T. I work for the American Lung Association, but I am sharing comments on behalf of Health Care Without Harm today.

As the organization leading the global movement for sustainable healthcare, Health Care Without Harm strongly opposes the proposed rule, "Strengthening Transparency in Regulatory Science." The rule would impede the Agency from upholding its mission to protect human health and the environment by limiting the use of scientific research.

It was the EPA's conclusions regarding the human health impacts of dioxin that lead the formation of our organization in 1996. Since then, we have led the charge to transition the U.S. healthcare sector away from medical waste incineration, the leading source of dioxin pollution.

In the United Sates, more than 5,000 medical waste incinerators were in operation in the mid-90s. Today, fewer than 16 medical waste incinerators remain. This work would not have been possible without the EPA relying on sound science to make determinations about the toxicity of dioxin pollution for human health.

Currently, Health Care Without Harm works with hospitals and health systems to transition to renewable energy and to prepare for the impacts of climate change. We look to the EPA to heed the science regarding the human health effects of fossil fuels and climate change when making decisions so that our hospitals are in the best position to protect their patients.

By artificially limiting the research it considers when making decisions, the EPA would endanger health and put lives at risk. We urge the EPA not to adopt this proposed rule.

MS. ORME-ZAVALETA: Thank you.

MR. AUERBACH: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. AUERBACH: My name is John, that's spelled A-U-E-R-B-A-C-H.

I am a public health practitioner. I've been a leader in the public health field for about 30 years. I was a city health commissioner, a state health commissioner, and an official at the Centers for Disease Control, and currently I am the President and Chief Executive Officer of Trust for America's Health, or TFAH.

TFAH is a non-profit, non-partisan public health and science-based organization that promotes optimal health for every person and community, and makes the prevention of illness and injury a national priority.

TFAH has been focused on issues like

clean air and clean water, because they are fundamental to ensuring that all Americans have the opportunity to live long and healthy lives. This is particularly crucial since we know that unhealthy air or contaminated drinking water disproportionately affect some of our more vulnerable subpopulations, including children, older adults, and lower income Americans who are more likely to include racial and ethnic minorities.

As a component of our mission to promote health we issue a series of reports every year that examine some of our nation's most pressing health issues, and we rely heavily on all available research and evidence to develop recommendations for decision makers on how they can most effectively respond to improve health.

For example, in 2011, TFAH and the Environmental Defense Fund released a report that analyzed the savings and health care spending associated with four different EPA regulations. In so doing, we relied on the EPA's own regulatory

impact analysis that measured reduced mortality, reduced incident of chronic bronchitis, reduced incident of heart attack, and decreased hospital emissions and emergency room visits. These studies estimated that nearly half a million lives could be saved by these four EPA standards alone.

Because of the importance of having access to such scientific data in order to protect the public's health, we oppose the "Strengthening Transparency and Regulatory Science" proposed rule. Research and evidence is the foundation of EPA's policies and has been necessary for success of laws like the Clean Air Act and improving and in saving lives from the dangers of air pollution.

Congress intentionally directed EPA to consider peer reviewed research under the Clean Air Act, and mandates regular reviews of the science to ensure that EPA is reviewing and considering the most up to date science. We believe that the proposal would prevent EPA from using the best science to inform decision-making, and the result would be weaker standards at the

expense of American's health. For example, the proposal would exclude several landmark air quality studies from the evidence base that EPA is permitted to consider, largely on the basis that these studies include confidential patient information that would make them less transparent under the constructs of the proposed rule.

The practical result would be weaker air pollution standards, despite the fact that the science behind these studies is pointing us in the opposite direction. The current methodology and system for review is sound, reliable, and has operated effectively for years. And that's why we have joined with the American Lung Association, the American Academy of Pediatrics, the American Public Health Association, and over 70 additional public health, medical, and academic organizations in opposing this regulation, this proposal.

As a long-term public health practitioner and the President of TFAH, I remain committed to ensuring that federal health policy and practices are guided by the evidence in a transparent and

accountable manner. EPA and other federal agencies should be no exception. We at TFAH look forward to working with congress, with the EPA and others, as we continue to advocate for policies and practices that uphold these principles and protect and promote the health of every American. Thank you very much.

MS. HALL: Thank you very much. If I could ask those that are in the room to please refrain from talking. There's a lot of whispering and it's distracting. If you do need to have a conversation, please step outside the room. Thank you.

Would Speaker Number 15, Harvey Fernbach and Speaker Number 16, Joseph Stanko, please approach the speaker's table. And Speaker Number 17, Peter Lurie and Speaker Number 18, Jamie Wells, please take a seat in the on-deck chairs.

What speaker number are you?

MR. STANKO: Sixteen.

MS. HALL: So, do we have Speaker Number 15? Harvey Fernbach?